PROGRAM DESCRIPTION

OFFICE OF MEDICAL POLICY

Center for Drug Evaluation and Research Medical Policy Council

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PURPOSE

This document describes the organization, membership, responsibilities, and procedures of the Medical Policy Council in the Center for Drug Evaluation and Research (CDER).

The CDER Medical Policy Council will provide senior support to the Center on medical policy development, including:

- Leadership oversight and medical policy management for the Center.
- Attention to, and management of, essential Center cross-cutting medical policy.
- Advocacy for the activities of this Council and its Working Groups.
- Promotion and coordination of communication both internally and externally on the medical policy decisions made by the Council.

BACKGROUND

The CDER Medical Policy Council provides a senior level forum to establish medical policy in CDER and its application to the new and generic drug review process, as well as other CDER programs. The Council will help to ensure that medical policy is implemented in a consistent manner throughout the Center.

The Council will meet on a regular basis to consider medical policy issues that are precedent setting and require senior management input to resolve.

Although the issue discussed by the Council may have been triggered by a specific product, the policy established by the Council will be applied to all similar products. Product-specific decisions will be remanded to the appropriate review division and/or office for follow-up and implementation.

For the purposes of this Council, medical policy generally concerns one or more of the following: (1) Clinical evidence of effectiveness or safety, (2) clinical study/trial design, (3) professional and patient labeling, (4) prescription drug promotion, (5) human subjects protection, (6) bioresearch monitoring, (7) good clinical practice, (8) counter-terrorism drug development (such as in the application of the Animal Rule; 21 CFR 314.600), and (9) postmarketing surveillance. To be considered by the Council, a medical policy issue typically would meet one or more of the following criteria:

- A novel medical policy issue requiring senior management input;
- An issue on which CDER seems to have taken inconsistent positions;
- An existing medical policy position that should be reconsidered in light of scientific or regulatory advances;
- A complex safety management issue requiring senior management input ;
- A medical policy that may be triggered by a specific product, but that will be applicable to other products; or
- Strategies for implementation of a new policy.

ORGANIZATION

Membership

The CDER Medical Policy Council includes the following.

- Chair: Associate Director for Medical Policy
- Members:
  - Center Director
  - Deputy Center Director for Clinical Science
  - Director, Office of New Drugs
  - Director, Office of Surveillance and Epidemiology
  - A division director from a review division of the Office of New Drugs to participate on the council for a one year term
  - A medical officer from a review division of the Office of New Drugs to participate on the Council for a one year term

Executive Committee members will be advised on Council meeting agendas and will be invited by the Council to attend and/or send a representative with expertise within their offices on the medical policy issue to be discussed.

Nominations for division director and medical officer will be provided by the Director, Office of New Drugs to the Council Chair for consideration.

The Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and any other relevant office within the Agency will be invited by the Council to send a representative to attend those meetings of known interest.

Working Groups

Working groups may be established by the Medical Policy Council if, among other things, there is:

- an identification by the Council that there is a need based on factors such as its knowledge of CDER operations and policies or new concepts and innovation; and
- direction by the Center Director to the Council to establish a new expert working group to achieve specific objectives (e.g., developing guidance).

Working groups will have a limited lifetime. The working groups will adjourn when they have successfully completed their goal or additional work is not required as determined by the Council.

RESPONSIBILITIES

Responsibilities of the Council.

- Direct the development of policy, regulations, and guidances intended to communicate and implement consistent, standard policies and procedures related to medical policy for internal and external use.
- Establish and oversee working groups to accomplish specific assessments and projects.
- Review work products (e.g., documents and recommendations) of working groups before they are circulated for clearance.
- Promote and coordinate internal and/or external communication of medical policy decisions when appropriate.
- Develop agency-wide communications on medical policy decisions when appropriate.

Responsibilities of the Council members related to their organizational units.

- Represent their organizational unit's views on issues under consideration by the Council.
- Identify relevant stakeholders and their concerns to the medical policy issue under discussion.
- Nominate representatives from their organization's unit to participate in working groups to implement activities deemed necessary by the Council to meet goals and objectives.
- Identify agenda items.
- Attend meetings regularly.

Responsibilities of the Council Chair.

- Provides leadership and direction to the Council.
- Reviews proposals and determines selection and prioritization of issues for consideration in conjunction when appropriate with Council members.
- Provides mediation and decision authority on issues that cannot reach consensus within the Council.
- Reviews nominations for the division director and primary medical officer positions on the Council.

Responsibilities of the Executive Secretary.

- Confirms meeting agendas and conduct meetings.
- Apprises the Chair of progress and activities.
- Promotes involvement and balanced participation of all members.
- Holds working group members accountable for completion of tasks.
- Reviews the briefs submitted and work with the individual or office to ensure that the brief is complete.
- Establishes working groups to address specific medical policy issues and challenges.
- Oversees working groups, holding them accountable for developing and executing plans.

Responsibilities of the Project Manager.

- Promotes relevant topics and content for agenda topics.
- Schedules meetings and communicate agenda prior to each meeting.
- Follows up on assignments and action items assigned to members.
- Prepares documents and papers as directed by the Executive Secretary.
- Serves as a focal point for the working groups.
- Maintains the rosters of the working groups.
- Maintains a repository that includes meeting notes, a log and status of issues discussed and actions assigned, and copies of Council decisions and actions.

Responsibilities of the working groups and their members.

- Develop project plans that include timelines and update the Council at regular intervals as designed by the Council.
- Confirm its objectives with the Council.
- Define workgroup member responsibilities.
- Provide work products to the Council in a timely manner.
- Respond to questions from the Council on specific issues.
- Advise and assist the Council in responding to agency staff and other queries.

Responsibilities of the individual and/or office seeking Council evaluation.

- Submits a proposal to the Executive Secretary for consideration by the Chair.

- Provides a 3-5 page brief to the Project Manager, if proposal accepted, 2 weeks before the Council meeting. The brief (see attachment 2) should provide all the necessary information to understand the medical policy issue to be discussed. The brief should also include questions for the panel members to consider and provide resolution.
- Identifies a lead from the office seeking Council evaluation.
- Submits a list of attendees representing viewpoints on the medical policy issue to be discussed, if proposal accepted, to the Project Manager.

PROCEDURES

1. Identification of issues.
    - Medical policy issues may be submitted by any Center staff member. Although the medical policy issue may be triggered by product-specific discussion and review, the medical policy issue presented to the Council will not be product-specific.
    - Medical policy issues may be developed from issues raised by the medical product industry, academia, political bodies, or other interested parties and brought to the attention of Center staff. The Council will consider whether opening a docket would be useful for soliciting outside stakeholder input on medical policy issues for discussion.
2. The Chair will review proposed medical policy issues and select and prioritize issues for consideration with appropriate input from Council members. Such proposals should be no more than one-two paragraphs and include the following:
    - The medical policy issue to be resolved.
    - The trigger that raised the medical policy issue.
    - The timeframe of when a response is needed.
3. If the proposal is not selected to be reviewed by the Chair or cannot be reviewed by the Council by the timeframe specified, the Executive Secretary will provide an explanation of the Council's decision. Reconsideration by the Council of such decisions can be requested.
4. If the proposal is selected, a pre-meeting may be scheduled between the Chair and/or Executive Secretary and the individual or office seeking Council evaluation to assist in refining the medical policy issue to be discussed.
5. The medical policy issue will be summarized in a Medical Policy Council brief (see attachment 2) prepared by the individual or office seeking Council evaluation.
6. A Council meeting will be convened.
    - Experts from CDER and Agency staff will be sought and invited to participate in the discussion.
    - The individual and/or office seeking Council evaluation will provide a ten minute overview of the medical policy issues at the beginning of the meeting.

- Decisions will be established through deliberation among all parties attending the Council meeting, reaching resolution through consensus.
- If the Council reaches a resolution to the medical policy issue brought to its attention at the scheduled meeting:
    - The Council will determine the appropriate communication for the medical policy reached and any action items recommended. This could include the following:
        - Decisional Memorandum
        - MAPP (new or revision to current MAPP).
        - Guidance (new, revision to current guidance, or addendum to current guidance)

      Until such documents are drafted and distributed, the Council will determine the appropriate communication strategy to disseminate decisions to CDER staff.
    - If the Council believes that a current MAPP, guidance or other document conveys the medical policy discussed at the meeting adequately, the Council may determine that training for CDER staff on the medical policy issue may be needed. The Council may recommend that the Division of Training and Development develop and implement such training.
    - The Council may establish a working group to explore the question further and draft the communication document.
- If the Council does not resolve a medical policy issue at the scheduled meeting:
    - the Council may establish a working group to explore the question further and return to the Council with recommendations for Council discussion on how to proceed; and
    - the Council may identify specific questions/concerns for an individual and/or office to research and provide answers, returning to the Council at a future meeting for further discussion.
- If the Council establishes a working group, offices and participants will be identified and included in the action items.
- Medical policy and action items will be archived in an electronic database accessible to all CDER staff.

7. If an individual or office identifies concerns or challenges in implementing the medical policy decision reached, the individual or office can request that the Council reconsider the decision.
    - Requests for reconsideration must be accompanied with an explanation on how by implementing the medical policy established by the Council would affect CDER decisions.
    - The Council, at the discretion of the Chair, may respond to the request using one of the following two options:
        - The Chair, with appropriate input from Council members and experts from CDER, may respond to the request in writing.

        - The agenda item may be re-introduced to the Council at a future meeting with the additional material in support of the request.
    - The request for reconsideration and the response will be archived with the initial medical policy decision reached.
8. The chair will meet with appropriate CDER staff to debrief on the Council meeting and to coordinate action items when needed.

AUTHORITY

The Council will have the following authority:

- Establish medical policy.
- Establish Working Groups.
- Provide direction and feedback to Working Groups.
- Ratify Working Group recommendations.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

ATTACHMENT 1 - Examples

The following are examples of medical policy issues and challenges that the CDER Medical Policy Council may address.

1. Obstacles to development of a non-inferiority margin (e.g., historic data outdated or historic data unavailable on current endpoint, or efficacy data unavailable on proposed comparator or non-inferiority margin undefined when new drug must be used in combination with other active agents).
2. Obstacles to development of an appropriate control regimen (e.g., the new product has already been adopted by the medical community as the standard of care for a new off-label indication).
3. Ethical obstacles to studying a drug in a high prevalence area where drug may not be deployed in the future (e.g., malaria prophylaxis).
4. Standards for use of the animal rule.
5. Approach to new indications proposed by sponsors, principles in deciding on medical relevance.
6. Approval of products that may benefit the community but not the individual (e.g., combinations to prevent emergence of microbial resistance, transmission blocking vaccines, interventions to reduce transmissibility of tuberculosis).
7. Standards of evidence for prophylaxis where efficacy may not be testable in man (e.g., prevention of anthrax, countermeasures to prevent poisoning).
8. Defining surrogate endpoints (e.g., when does a surrogate become a validated clinical endpoint).

ATTACHMENT 2 - Template

CDER Medical Policy Council Brief
Template

Purpose - The CDER Medical Policy Council Brief is a "stand alone" document of a medical policy issue(s) that requires resolution from the CDER Medical Policy Council. It should convey the medical policy issue to be resolved, the trigger that raised the medical policy issue, and the timeframe of when a response is needed. The document should follow the CDER Reviewer Style Manual, be no more than three-five pages, and provide all the necessary information to understand the medical policy issue to be discussed.

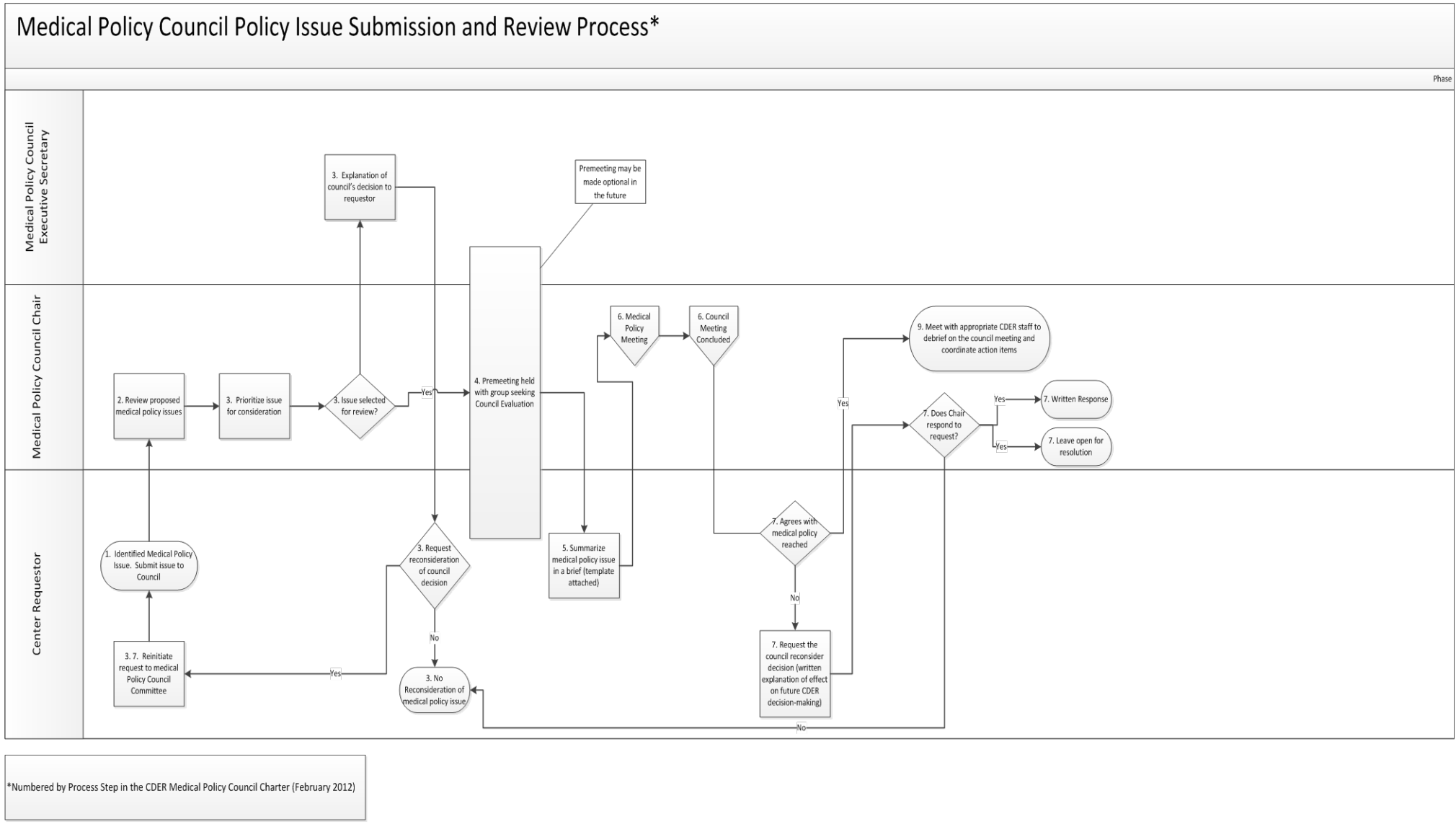
Introduction - Provide an overview of the medical policy issue to be resolved.

Background - Describe scientific, clinical and regulatory areas that address the medical policy issue to be resolved. If applicable, include any areas and issues that have been raised, the regulation and/or guidance that have an impact on the medical policy issue, any considerations and advice already provided in discussions with the sponsor, and any other important aspect, such as previous advice and precedent given to other sponsors or staff, that would affect the resolution to be reached. The information should include ideas, including any differing opinions, on how the medical policy should be implemented.

Questions to be Considered by the Council - List the questions that the Council should consider in response to the medical policy issue to be resolved. The questions should be general, applying to all drugs and/or biological products or a group of drugs and/or biological products. Questions should not be product-specific.

Presentation - Provide all presentation materials to be used by the individual or an identified lead from the Office seeking Committee evaluation. The presentation will be limited to no more than ten minutes and may only reference materials provided in the brief or brief attachments (see Attachments). A PowerPoint presentation is not required.

Attachments - Attach any additional background material, such as reviews, guidance, or regulations. Attachments are not required, but such attachments are supplementary to the Council brief.


Medical Policy Council Policy Issue Submission and Review Process*
Phase
Medical Policy Council Executive Secretary
Medical Policy Council Chair
Center Requestor
3. Explanation of council's decision to requestor
Premeeting may be made optional in the future
2. Review proposed medical policy issues
3. Prioritize issue for consideration
3. Issue selected for review?
Yes
4. Premeeting held with group seeking Council Evaluation
6. Medical Policy Meeting
6. Council Meeting Concluded
9. Meet with appropriate CDER staff to debrief on the council meeting and coordinate action items
Yes
7. Does Chair respond to request?
Yes
7. Written Response
Yes
7. Leave open for resolution
1. Identified Medical Policy Issue. Submit issue to Council
3. Request reconsideration of council decision
5. Summarize medical policy issue in a brief (template attached)
7. Agrees with medical policy reached
No
3. 7. Reinitiate request to medical Policy Council Committee
Yes
No
3. No Reconsideration of medical policy issue
7. Request the council reconsider decision (written explanation of effect on future CDER decision-making)
No
*Numbered by Process Step in the CDER Medical Policy Council Charter (February 2012)